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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/783,080
Filing Date: February 20, 2004
Appellant(s): MANEGOLD ET AL.

Cynthia L. Foulke
Reg. No. 32,364
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10/17/08 appealing from the Office action mailed 10/17/07.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments after Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,599,554	MAJETI *et al.*	6-2003
2005/001847	BALLARD *et al.*	2-1998
WO (2004/096174)	KULKARNI *et. al.*	3-2001

Note: Upon further consideration and in view of Appellant's arguments filed on 04/17/08, the rejections made under 35 USC 112.2 are hereby withdrawn.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 1-9 and 14-20 are rejected under 35 U.S.C. 103(a) as being Unpatentable over Majeti (US patent No. 5,599,554) in view of Kulkarni et al. (WO 2004/096174 A1).

2. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballard et al. (US Pg Pub. 2005/0013847 A1) in view of Kulkarni et al. (WO 2004/096174 A1).

1. Claims 1-9 and 14-20 are rejected under 35 U.S.C. 103(a) as being

Unpatentable over Majeti (US patent No. 5,599,554) in view of Kulkarni et al. (WO 2004/096174 A1).

Majeti discloses transdermally or transmucosally administrable composition in the form of mucoadhesive or bioadhesive films for the treatment and /or smoking withdrawal symptoms (abstract and column 2, lines 18-23 and column 3, lines 17-20). The composition comprises caffeine, which is slightly soluble in water and alcohol (column 3, lines 17-20). The various amounts of caffeine are used in the dosage form are listed on column 4, lines 10-23). Majeti further suggests that the amount of caffeine and frequency of administration may vary depending on the carrier and the personal needs of the user (column4, lines 24-26). Majeti discloses that a variety of additional pharmaceutically acceptable ingredients may be added such as disintegration agents (column 6, lines 25-27). The teachings of Majeti have been discussed above. Majeti does not specifically disclose the claimed percentage or amount of caffeine in the composition. It is to be noted that with respect to the claimed percentages and amount of caffeine, it is the position of the examiner that optimization of such parameters would have been within the purview of a skilled artisan at the time the invention was made by performing manipulative experimentation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

The teachings of Majeti have been discussed above. Majeti does not disclose dispersing an active ingredient in an aqueous environment. However, Kulkarni discloses

fast dissolving orally consumable films containing pharmaceutically active agents (abstract). On pages 20-40 in specific examples, Kulkarni discloses dextromethorphan HBr mixed and dissolved in water to yield an aqueous phase. On page 2, Kulkarni discloses that the invention discloses a method of preparing a supple, non-self adhering film especially suitable for oral delivery of active ingredient.

It would have been thus obvious to the one of ordinary skilled in the art to include the step/method of dissolving the active ingredient in aqueous phase based on the teachings of Kulkarni and combine it with the teachings of Majeti et al. in order to achieve the claimed orally dissolvable film. A skilled artisan would have been motivated to prepare an active containing dissolvable film based on the teachings and guidance provided by Kulkarni and Majeti et al. with a reasonable expectation of success. It should be noted that no specific amounts of active agent or any specific agent has been disclosed in claim 1, since the prior art discloses caffeine in the prior art, the limitations of having solubility parameters as less than about 1g/4mL reads on the prior art and the dissolving characteristics of the film would have been expected to be same as the claimed limitations absent evidence to the contrary.

2. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballard et al. (US Pg Pub. 2005/0013847 A1) in view of Kulkarni et al. (WO 2004/096174 A1).

Ballard et al. discloses a delivery system comprising a homogenous, thermoreversible gel film comprising film formers, active substance, bulking agent and pH controlling agent along with the process of manufacture of such films (abstract and page 1 paragraph [0002]). Ballard et al. disclose variety of film forming agents which includes modified starches (see page 1 paragraph [0004 and page 2, paragraph [0021]). Various modified starches are listed on page 3, paragraph [0024] including the claimed hydroxylpropylated starches. The films as disclosed contain active substances such as oral care agent, a breath freshening agent, a pharmaceutical agent, a nutraceutical, vitamin, a flavorant or a food (see page 2 paragraph [0018] and claim 2). Ballard et al. further disclose that the water content in the film ranges from 5-15% (page 3, paragraph [0028]). The process of manufacturing which involves mixing, coating, drying and molding or casting into films have been detailed on page 3 paragraph [0031] and [0044]. Ballard et al. also teach **caffeine** in paragraph [0102] on page 9. Ballard et al. also teach the claimed drugs with low solubility, since Ballard et al. teach caffeine and generic “pharmaceutical agent” and also “vitamins”, which then includes lipophilic (vitamin A, E, D and K) compounds also, it would have been obvious to one of ordinary skill in the art to select these lipophilic compounds with low solubility such as caffeine from the teachings of Ballard et al. with a reasonable expectation of success.
The teachings of Ballard have been discussed above.

Ballard does not disclose dispersing an active ingredient in an aqueous environment. However, Kulkarni discloses fast dissolving orally consumable films containing pharmaceutically active agents (abstract). On pages 20-40 in specific

examples, Kulkarni discloses dextromethorphan HBr mixed and dissolved in water to yield an aqueous phase. On page 2 Kulkarni discloses that the invention discloses a method of preparing a supple, non-self adhering film especially suitable for oral delivery of active ingredient.

It would have been thus obvious to the one of ordinary skilled in the art to include the step/method of dissolving the active ingredient in aqueous phase based on the teachings of Kulkarni and combine it with the teachings of Ballard et al. in order to achieve the claimed orally dissolvable film. A skilled artisan would have been motivated to prepare an active containing dissolvable film based on the teachings and guidance provided by Kulkarni and Ballard et al. with a reasonable expectation of success.

Ballard does not specifically disclose the claimed percentage or amount of caffeine in the composition. It is to be noted that with respect to the claimed percentages and amount of caffeine, it is the position of the examiner that optimization of such parameters would have been within the purview of a skilled artisan at the time the invention was made by performing manipulative experimentation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It should be noted that no specific amounts of active agent or any specific agent has been disclosed in claim 1, since the prior art discloses caffeine in the prior art, the limitations of having solubility parameters as less than about 1g/4mL reads on the prior art and the dissolving characteristics of the film

would have been expected to be same as the claimed limitations absent evidence to the contrary.

(10) Response to Rejection 1:

Appellants argue that there is no disclosure of a dissolvable film in Majeti or that any active, let alone actives that are not very soluble like caffeine, may be administered using a dissolvable film as disclosed and claimed by Appellants.

Appellant's arguments are not persuasive because Majeti does disclose bioadhesive film comprising caffeine. Majeti discloses bioadhesive films for the treatment and /or smoking withdrawal symptoms (abstract and column 2, lines 18-23 and column 3, lines 17-20). The composition comprises caffeine, which is slightly soluble in water and alcohol (column 3, lines 17-20). The various amounts of caffeine are used in the dosage form are listed in column 3, lines 30-35 and in column 4, lines 10-23). The reference teaches caffeine or caffeine equivalent is delivered in an amount of from about 10 mg to about 250 mg, preferably from about 50 mg to about 200 mg or 75 to 10 mg and suggests that the amount of caffeine and frequency of administration may vary depending on the **carrier and the personal needs of the user (column 4, lines 24-26).** Majeti also teaches that while the choice of trandermal or transmucosal carrier is not critical to the present invention, the carrier or carriers chosen must be suitable for administering the nicotine or caffeine so that the **desired blood levels of**

these compounds are achieved. Therefore, Appellants argument that there is no disclosure of a dissolvable film in Majeti or that any active, let alone actives that are not very soluble like caffeine, may be administered using a dissolvable film as disclosed and claimed by Appellants is not persuasive.

Appellants argue that while Kulkarni discloses dissolvable films, it is silent as to whether actives having low levels of solubility can be incorporated into a dissolvable film at levels where they exert a desired effect when administered. There is nothing in the combined disclosure that would suggest that actives having a low level of solubility, such as caffeine, could be delivered using the dissolvable film of Kulkarni. The combined disclosures would not have suggested to one of ordinary skill in the art that the caffeine of Majeti could be administered using the film of Kulkarni. The invention of claims I-9, I4 and 15 would not have been obvious to one skilled in the art from the combined disclosures of Majeti and Kulkarni.

Appellant's arguments are not persuasive.

While it is true that Kulkarni does not specifically teach that actives with low solubility can be incorporated in dissolvable film, however, Kulkarni is not cited for such limitation rather Kulkarni is cited and combined for the teachings of the process step comprising the dissolution of an active ingredient in an aqueous environment.

In response to Appellant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the

references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Appellant argues that Caffeine has a low level of solubility, there is nothing in the combined disclosures of Majeti and Kulkami to suggest that caffeine, in the amounts required in claims 14 and 15, could be administered using a dissolvable film, as claimed by Appellants. The combined disclosures would not have suggested to one of ordinary skill in the art that the caffeine of Majeti could be administered using the film of Kulkami and thus the reference is not obvious over the combination of prior art.

Appellant's arguments are not persuasive. Majeti teaches various amounts of caffeine. The various amounts of caffeine are used in the dosage form are listed in column3, lines 30-35 and in column 4, lines 10-23). The reference teaches caffeine or caffeine equivalent is delivered in an amount of from about 10 mg to about 250 mg, preferably from about 50 mg to about 200 mg or 75 to 10 mg. Optimization of various amounts would have been obvious to one of ordinary skill in the art at the time the invention was made by doing experimental manipulations absent evidence to contrary. Appellants have not provided any unexpected results associated with the claimed amounts of caffeine. Appellant is reminded that where the general conditions of the claims are met, burden is shitted to Appellant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

(11) Response to Rejection 2:

Appellant argues that Ballard discloses gel films formed of structured alginate used to deliver actives for oral care to the oral cavity. Ballard does not teach or even suggest that the active can be solubilized or dispersed in an aqueous environment and mixed with film forming agents to form a dissolvable film. Kulkami adds nothing to the disclosure of Ballard to render the claimed invention obvious.

Appellant's arguments are not persuasive. In response to Appellants argument that Ballard does not teach or even suggest that the active can be solubilized or dispersed in an aqueous environment and mixed with film forming agents to form a dissolvable film, It should be noted that Ballard was not cited for solubilizing active in aqueous environment rather Kulkarni was cited for this specific process step since Kulkarni explicitly teaches process of dissolving active ingredient into aqueous medium. In one of the embodiments, Kulkarni states on page 14, lines 10-15 a method of preparing the consumable film, it may be desirable to first form the film forming mixtures by first hydrating the water soluble polymer with water and aqueous phase is then prepared by dissolving the other water soluble ingredients such as antitussive agent and mucosa coating agent etc. Examples 1 and 2 also describe the mixing of **active ingredient with water (see page 18, step A).**

Appellants argue while Ballard and Kulkami disclose films useful in administering actives, there is no disclosure or suggestion that actives having low levels of solubility

can be incorporated into a dissolvable film at levels where a desired effect is obtained following administration. There is no disclosure that would suggest that actives, such as caffeine, could be successfully delivered using the film of Ballard or Kulkami so as to render the claimed invention obvious. The invention of claims 1-20 would not have been obvious to one skilled in the art from the combined disclosures of Ballard and Kulkami.

Appellant's arguments are not persuasive. In response to appellants argument that, there is no disclosure or suggestion that actives having low levels of solubility can be incorporated into a dissolvable film at levels where a desired effect is obtained following administration, the Examiner respectfully states that Ballard does teach actives with low levels of solubility and Ballard also discloses an active with low solubility such as caffeine (which has been claimed in instant dependent claim 6) while disclosing dissolvable film (see paragraph [0102] on page 9). Since, Kulkarni teaches utilization of any active agent in the dissolvable film and teaches the process of dissolving an active ingredient in an aqueous environment, one of ordinary skill in the art would have been motivated to prepare a dissolvable film comprising an active with low solubility such as caffeine and come to the claimed invention with a reasonable expectation of success.

Appellants argue that "Claim 10 is directed to an active-containing film comprising the active and film forming ingredients, which film forming ingredients comprise a starch component, at least 85% of which is a modified starch. Claim 11 limits the modified starch to a hydroxyalkylated starch, a succinated starch, or mixture

thereof. Caffeine has a low level of solubility, there is nothing in the combined disclosures of Ballard and Kulkarni to suggest that caffeine, which has a low solubility level, could be administered in amounts effective to impart a desired action using a dissolvable film that comprises starch. The invention of claims 10 and 11 would not have been obvious to one skilled in the art from the combined disclosures of Ballard and Kutkami.

Appellant's arguments are not persuasive. Ballard teaches variety of film forming agents which includes modified starches (see page 1 paragraph [0004 and page 2, paragraph [0021]). Various modified starches are listed on page 3, paragraph [0024] including the claimed hydroxylpropylated starches. Ballard also teaches lipophilic compounds with low solubility, as such incorporation of **caffeine** (see page 9, paragraph [0102]) which has low solubility, would have been obvious to one of ordinary skill in the art since Ballard teaches incorporation of lipophilic active ingredients and Ballard teaches the modified starches wherein both the prior art s are geared towards making dissolvable film.

Appellants argue that caffeine has a low level of solubility, there is nothing in the combined disclosures of Ballard and Kulkami to suggest that caffeine, in the amounts required in claims 14 and 15, could be administered using a dissolvable film, as claimed by applicants. The invention of claims 14 and 15 would not have been obvious to one skilled in the art from the combined disclosures of Ballard and Kulkarni.

Appellant's arguments are not persuasive. Optimization of amounts would have been within the purview of a skilled artisan at the time of instant invention because both the prior art teach amounts of active ingredients (see page 9, paragraph [0102]) absent evidence of unexpected results.

Appellants argue that: there is no disclosure of administering actives to by application of a film to traumatized tissue in either of Ballard or Kulkarni; as such their combination also fails to suggest the claimed subject matter. The invention of claims 18 and 19 would not have been obvious to one skilled in the art from the combined disclosures of Ballard and Kulkami.

Appellant's arguments are not persuasive. Since prior art teaches various active ingredients in dissolvable films, it is the position of the examiner that administration of such film with pharmaceutically active ingredient would have been obvious to one of ordinary skill in the art at the time of instant invention.

(14) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Snigdha Maewall/

Examiner, Art Unit 1612

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